

## REMARKS

### I. Status of the Application

Claims 27-45 are pending in the application. Applicants gratefully acknowledge the Examiner's withdrawal of the objection to claim 37, the rejection of claims 27, 28 and 33 under 35 U.S.C. § 102(b) as anticipated by Kokubo et al., and the rejection of claims 27, 28 and under 35 U.S.C. § 102(e) as anticipated by Li. Claims 27-33 and 36-38 stand rejected under 35 U.S.C. § 102(e) as anticipated by Leitao (U.S. Patent No. 6,069,295). Claims 34, 35, 44, and 45 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Leitao. Claims 27, 28, and 32-36 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Li (U.S. Patent No. 6,139,585). Claims 27 and 28 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Nonami et al. (U.S. Patent No. 5,125,971).

Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention. Support for the amendments can be found in the specification and the claims as originally filed. Support for the amendment to claim 39 to recite that the coating has an average bond strength to the implant of between 40 to 65 Mpa can be found in the specification at least at page 19 line 36 to page 20 line 2, which explicitly recites this claim limitation. The amendments presented herein add no new matter. Attached hereto is a marked-up version of the changes made to the claims captioned "Version Of Amendments With Markings To Show Changes Made."

Applicants respectfully request entry and consideration of the foregoing amendments, which are intended to place this case in condition for allowance.

## II. Claims 27-33 and 36-43 are Novel over Leitao

At page 2, paragraph 4 of the present Office Action, claims 27-33 and 36-43 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Leitao (U.S. Patent No. 6,069,295). The Examiner asserts that although Leitao does not explicitly teach the claimed bond strength between the coating and the implant of between 40 to 65 MPa, the device of Leitao would necessarily have the same bond strength as the claimed bond strength because Leitao uses the same ions as Applicants. Applicants respectfully traverse this rejection.

The MPEP states that “when a reference is silent about the asserted characteristics, such gap in the reference may be filled with recourse to extrinsic evidence...[which] *must make clear* that the missing descriptive matter is *necessarily present* in the thing described in the reference” (MPEP § 2131.01 part III, emphasis added).

Leitao reports no adhesion strengths. The Examiner has failed to present any reference which provides evidence that the bond strength of the implants taught by Leitao is *necessarily* between 40 to 65 MPa.

In contrast, the art cited by the Examiner would lead one of skill in the art to believe that the bond strength of implants coated with magnesium, calcium and phosphate ions is highly unpredictable. For example, the implant of Kokubo et al. formed by soaking a substrate in an aqueous solution containing *calcium, phosphate and magnesium ions* just like Leitao, has a *maximum bond strength of 11 MPa*, which is much lower than Applicants’ claimed range. Based on the coating of Kokubo et al. which comprises magnesium, calcium and phosphate and a maximum bond strength of 11 MPa, the Examiner *cannot conclude* that the coating of Leitao, which

also comprises magnesium, calcium and phosphate, *necessarily has* a bond strength of 40 to 65 MPa, as required to anticipate Applicants' claimed subject matter.

Thus, Leitao fails to teach all of Applicants' claim limitations. Accordingly, Applicants respectfully request that the 35 U.S.C. § 102(e) rejection of claims 27-33 and 36-43 be reconsidered and withdrawn.

### **III. Claims 34, 35, 44, and 45 are Nonobvious over Leitao**

At page 3, paragraph 5 of the present Office Action, claims 34, 35, 44, and 45 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Leitao. With regard to claims 34 and 35, in the Office Action dated May 22, 2001, the Examiner asserts that Leitao teaches coating a metal or ceramic substrate with an amorphous calcium phosphate layer, which can be made from a combination of calcium and phosphate ions, together with hydroxide, magnesium, and/or chloride ions, and that the calcium phosphate layer may also form hydroxyapatite. The Examiner further asserts that Leitao teaches pre-treatment of the substrate, prior to coating of said implant, using a chemical surface treatment, such as treatment with a strong mineral acid, or a mechanical surface treatment, such as sanding or scoring. Regarding claims 44, and 45, the Examiner's rejection is for the same reasons as applied to claims 34-35. At page 6 of the present Office Action, the Examiner further asserts that the bond strength of Leitao is *inherently* within the range claimed by Applicants. Applicants respectfully traverse this rejection.

As discussed above, Leitao fails to teach a coated implant comprising a coating having an *average bond strength* to the implant *of between 40 to 65 MPa*. For the reasons set forth above, Applicants submit that no reference of record has been identified which cures the deficiency of

Leitao. The Federal Circuit has held that “[I]nherency and obviousness are different concepts” and “[t]hat which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.” *In re Dillon*, 919 F.2d 688, 718 (1990). Thus, Applicants respectfully submit that the Examiner cannot base an obviousness rejection upon an inherent bond strength that is unknown (i.e., not taught by the reference) and not supported in the present rejection by a secondary reference.

Accordingly, Applicants respectfully request that the Examiner withdraw the obviousness rejection.

#### **IV. Claims 27, 28 and 32-36 are Nonobvious over Li**

At page 3, paragraph 6 of the present Office Action, claims 27, 28 and 32-36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Li (U.S. Patent No. 6,139,585). The Examiner asserts that Li teaches a coated implant wherein the coating comprises calcium ions, phosphate ions, magnesium ions and carbonate ions, and that the implant substrate may be metal, ceramic, or polymer (Office Action dated May 22, 2001). The Examiner further asserts that Li teaches that the adhesion strength of the coating to a polished substrate is believed to be in excess of 30 MPa, and that the range of 30 MPa overlaps the range claimed by Applicants. The Examiner states that overlapping ranges are prima facie evidence of obviousness and that it would have been obvious to one of skill in the art to have selected the portion of Li’s range that corresponds to the claimed range.

The Examiner states that Li teaches the use of carbonated calcium phosphate and a coating thickness of 0.005 to 50 microns. The Examiner also states that the second coating taught by Applicants in claim 36 differs from Li only in requiring two layers whereas Li teaches one layer, and concludes

that it is well-settled that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced.

Applicants respectfully traverse the rejection. The Examiner states that she must take the teachings of Li at face value. While Applicants generally agree, the Examiner is not allowed to ascribe teachings to Li that are not supported by evidence, that would not be understood by one of skill in the art, or that simply are not there.

Li does not teach an adhesion strength range. Instead, Li teaches an open-ended variable, i.e., the adhesion strength of the coating taught by Li et al. is “believed to be in excess of 30 MPa” (column 6, lines 44-45). Li does not teach how much in excess the adhesion strength actually is. Applicants respectfully submit that the claimed adhesion strength of Li is hopelessly indefinite since Li identifies no upper limit for its adhesion strength. Is the upper limit 31 MPa, 35 MPa, 1000 MPa or greater? One of skill in the art simply does not know because no test data is provided by Li, and because the adhesion strength of coatings similar to Li’s is demonstrated by the art to be unpredictable. See the 11 MPa bond strength of Kokubo et al., cited by the Examiner. Accordingly, one of skill in the art would not know whether Li’s adhesion strength was between 40 to 65 MPa, as claimed by Applicants. Applicants submit that if it was, Li would have reported it.

Thus, Li fails to teach all of Applicants’ claim limitations. Accordingly, Applicants respectfully request that the Examiner withdraw the obviousness rejection.

V. **Claims 27 and 28 are Nonobvious over Nonami et al.**

At page 4, paragraph 7 of the present Office Action, claims 27 and 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nonami et al. (U.S. Patent No. 5,125,971). The Examiner asserts that Nonami et al. teaches an implant substrate comprising calcium, phosphate and magnesium ions joined with a coating material of the same make-up, and that the bond strength between the two materials is 30-1000 MPa, overlapping the range set forth by Applicants. The Examiner states that the materials of Nonami et al. promote the formation of bones. The Examiner admits that Nonami et al. does not teach solution coating, but asserts that a rationale was provided by the Examiner tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process. The Examiner concludes that the burden shifts to Applicants to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. Applicants respectfully traverse this rejection.

Nonami et al. is directed to superplastic forming ceramic materials and sintered composite bodies, which requires exposure of the ceramics to very high heat. In contrast, Applicants' claims require the unobvious physical difference of crystals nucleated directly onto the implant. Nonami et al. neither teaches nor suggests crystals nucleated directly onto the implant. The structure of the coating on the coated implant obtained by direct nucleation differs from the structure obtained by superplastic forming. For example, x-ray diffraction spectra of the ceramics taught by Nonami et al. (Figs. 5 and 6) are very different from Applicants' (Fig. 8). The material of Nonami has sharp peaks between 25 and 35 degrees and only minimal peaks between 35 and 40 degrees. Applicants' ceramics, however, have sharp peaks between 35 and 40 degrees, and minimal peaks between 25 and

35 degrees. Thus the materials of Nonami et al. and the coated implants claimed by Applicants have very different structures.

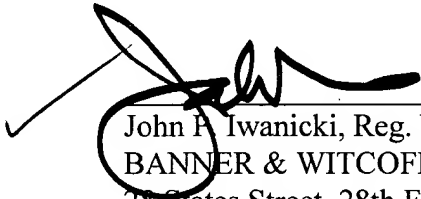
As Nonami et al. fails to teach all of Applicants' claim limitations, Applicants respectfully request that the Examiner withdraw the obviousness rejection.

**VI. CONCLUSION**

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicants' attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7111.

Respectfully submitted,

Dated: November 4, 2002

  
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**Version Of Amendments With Markings To Show Changes Made**

**In the claims:**

Please amend the claims as follows:

39. (Amended) A coated implant comprising an implant and a coating, wherein said coating comprises a deposit of octacalcium phosphate crystals nucleated directly onto the implant from solution with the coating having an average bond strength to the implant of between 40 to 65 Mpa, and wherein said coating induces formation of bone cells from progenitor cells.